

REMARKS

The following remarks are submitted with the above claim amendments to be fully responsive to the Official Action dated August 6, 2007. It is submitted that this response is timely filed within the shortened statutory period as extended by the one-month Request for Extension of Time filed concurrently herewith. It is believed that no other fee is required in filing this Amendment. However, should any fees be required, the Commissioner is authorized to charge Kagan Binder Deposit Account No. 50-1775 and thereafter notify us of the same. Reconsideration of all outstanding grounds of the rejection and allowance of the subject application are believed in order and respectfully requested.

Claims 1-11 are pending in the above-identified patent application. Claims 1-4 were previously withdrawn. Claims 5-11 have been rejected. Applicants presently cancel claims 5-7 and amend claim 8 as indicated above. Applicants also add new claims 12 and 13. Applicants submit that any amendment to the claims, and the new claims, are fully supported by the application as originally filed and that such amendments and new claims do not present addition of new matter.

In the Official Action, claims 5-11 were rejected under 35 U.S.C. 102(e) as being anticipated by Macoviak et al. (U.S. Patent No. 6,395,014; hereinafter "Macoviak").

Macoviak teaches a device used during cardiopulmonary bypass surgery that is an arterial perfusion catheter with a deployable cerebral embolic protection assembly (CEPA) for protecting a patient from adverse effects due to emboli that may be dislodged during surgery (col. 1, lines 22-26). Various embodiments of the device are disclosed, with the embodiment discussed in the Official Action being the one illustrated in Figure 16. The device in Figure 16 is described as having a CEPA in the form of an embolic filter assembly 642 combined with a selectively deployable external flow control valve 644 (col. 10, lines 43-46). The selectively deployable external catheter flow control valve 644 is not described in the specification, but rather three U.S. patent applications (now U.S. Pat. Nos. 5,827,237 ("237 patent"), 6,059,757 ("757 patent"), and 6,896,690 ("690 patent")) were incorporated by reference for their descriptions of such valves (col. 10, lines 55-60).

Generally, the '237, '757 and '690 patents describe a valve 10 (e.g., see Fig. 2 of '757 patent) coupled to a catheter 14 at an exterior 16 of the catheter 14, and including leaflets 22 with distal ends of the leaflets 22 attached using advancement and retractions members 18 ('757 patent: col. 7, lines 22-31). While placed in a circulatory vessel, antegrade blood flow causes the leaflets 22 to be displaced toward the catheter ('757 patent: col. 7, lines 64-66), allowing blood

to flow through the vessel ('757 patent: col. 8, lines 32-37). Retrograde blood flow causes the valve 10 to "puff" and the leaflets 22 to move toward and against the wall of the circulatory vessel, effectively preventing blood from flowing back ('757 patent: col. 8, lines 23-25, 28-31).

In the '237, '757 and '690 patents, the valves are mounted on catheters (e.g., Fig. 6 of '757 patent). Macoviak also describes the selectively deployable external catheter flow control valve 644 as being mounted on an elongated catheter shaft 646, and specifically upstream from the embolic filter assembly 642 (col. 10, lines 48-51).

As one point of distinction, the valved filter device of claims 8-11 of the present application is shown and disclosed as having a parabolic cone shaped membrane 1002 (having an apex and base), connected at the apex to a catheter and at the base at 3-4 discrete points around its circumference to a valve seating retaining ring 1006 (p. 53, lines 9-17). The valve seating retaining ring, as can be seen in Figures 25, 29-35, is also attached to the open end of the filter 1008. The valve seating retaining ring 1006, although collapsible, can expand to the internal circumference of the vessel in which it is placed (p. 53, lines 16-18). Therefore, when blood attempts to pass in retrograde fashion through the valve, the membrane 1002 inflates and compresses against the inner surface of the valve seating retaining ring 1006 (p. 53, lines 19-22), which compresses the ring 1006 (and attached filter tube 1008) against the vessel wall and thereby prevents reversal of blood flow (p. 54, lines 1-4). The filter tube 1008, being attached to the ring 1006, also moves outward toward the vessel wall, and is able to effectively filter blood running through the vessel during both diastole and systole.

Although original claim 8, including the feature regarding the connection of the membrane and the filter tube, was distinct from the Macoviak, claim 8 is amended as indicated above to clarify the distinguishing connection feature. The amended claim 8 includes the limitation from original claim 10, which is, therefore, cancelled. In dependent claims, which are new claims 12 and 13, further limitations regarding the connection of the membrane to the inner surface of the valve seating retaining ring (claim 12) and the resulting coordinated movement of the membrane, ring and tube (claim 13) are also added.

Claims 5-7 have also been canceled as indicated above, and are, therefore, not addressed with regard to the 102(e) rejection.

Thus, regarding the rejection of record based upon the Macoviak reference under section 102(e), it is submitted that the presently claimed invention is patentably distinct. Accordingly, it is submitted that claims 8-9, and 11 are patentably distinct from the Macoviak reference, and as


such, it is respectfully requested that the 102(e) rejection with respect to original claims 8-9, and 11 be withdrawn.

Claims 5-7 were rejected under obviousness-type double patenting with respect to claims 1 and 3 of U.S. Patent No. 6,896,690.

Regarding the non-statutory obviousness-type double patenting rejection with respect to claims 5-7, the subject claims have been canceled. Thus, the non-statutory obviousness-type double patenting rejection of original claims 5-7 is moot.

Accordingly, it is submitted that claims 8-9, and 11, and new claims 12 and 13, are currently in condition for allowance, a notice of which is earnestly solicited. If the Examiner finds any issue remaining after consideration of this response, the Examiner is invited to contact the undersigned, at the Examiner's convenience, in order to expedite any remaining prosecution.

Respectfully Submitted,

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